CTRP User Call
Data Table 4

NIH NATIONAL CANCER INSTITUTE

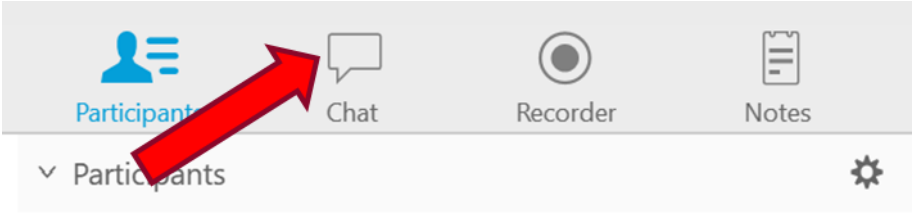
July 18, 2018

CTRP User Calls
Focus on CTRP Generated Data Table 4 for Interventional Trials

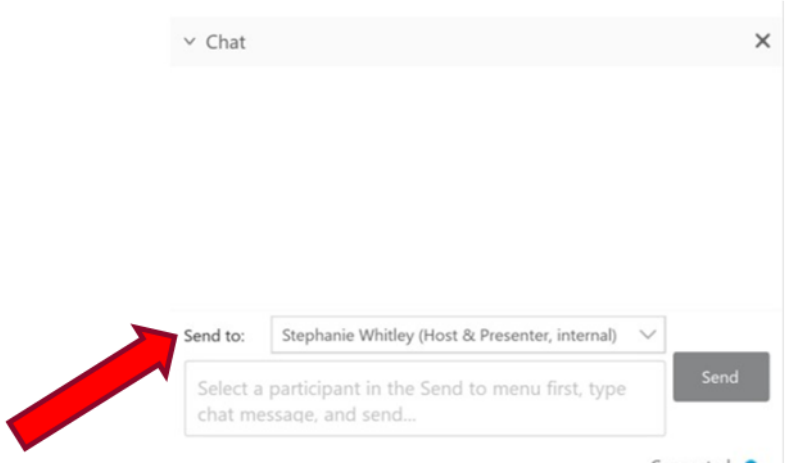
- Welcome
- Purpose
- Future Calls
  - Frequency
  - Agenda Items

CTRP User Calls
Submitting CTRP DT4 Questions to WebEx Host (Chat box)

- Click the Chat icon in the upper right portion of the screen



- Select Send to recipient: WebEx Host

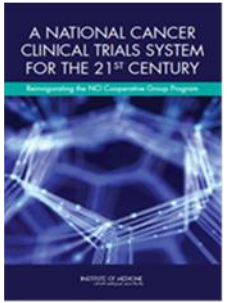


Agenda for Today's Call

- NCI's Clinical Trials Reporting Program (CTRP): Overview
  - Rationale
  - Source of Clinical Trials
  - Distribution and Use of CTRP Data
- CTRP-generated Data Table 4 (DT4) Updates
  - Rationale
  - Status - CTRP DT4 for Interventional Trials for Non-Competing Applications FY18
  - Support and Recent CTRP Updates
  - Next Steps

CTRP: Rationale for Development

- The need for a single central repository of NCI-supported clinical trials has been long standing
- The Clinical Trials Working Group (2005) and the Institute of Medicine (2010) reports noted:
  - NCI did not have a single electronic database that captured all NCI supported trials and their accrual
  - Trials supported by grants (R01, R21, P01, SPORE, etc.) and institutionally-supported trials using NCI-funded Cancer Center infrastructure resources were particularly difficult to identify
  - Available databases did not allow NCI to:
    - Monitor accrual for all trials
    - Identify gaps and duplicative studies
    - Effectively prioritize clinical trials



CTRP: Key Attributes

- Existing databases (e.g., ClinicalTrials.gov) do not fulfill all purposes envisioned for an NCI clinical trials database
- CTRP addresses these gaps through unique features:
  - Consistent terminology and standardized data elements to optimize search and retrieval of cancer clinical trials information
  - Inclusion of structured biomarker information
  - Quarterly reporting of accrual, including participant-level demography
  - Standard representation of persons and organizations
  - Identification of associated NCI awards and contracts
  - Regular updates to reflect protocol amendments, as well as participating site and status changes

CTRP: Scope and Content

- Scope of trials
  - All *interventional* trials, regardless of funding source, conducted at one or more NCI-Designated Cancer Centers
  - Includes trials sponsored (per FDAAA) by NCI as well as trials sponsored by other entities (e.g. institutions, industry)
- Accrual reported at least quarterly for all active trials
  - Patient level accrual data except for industrial trials
  - Cumulative accrual data for industrial trials
- CTRP currently accepts, but does not require, data on *observational* trials and *ancillary correlative studies*

CTRP: Data Sources

CTEP

Cancer Centers/Awardees

DCP

CCR

ClinicalTrials.gov

CTRO

CTRP

CTRP: Data Distribution and Use

Cancer Centers/Awardees

Reports, e.g. CTRP Generated DT4

CTEP

DCP

CTRO

CTRP

CCR

ClinicalTrials.gov

Cancer.gov

API Users

Rationale for CTRP-Generated Data Table 4

- Eliminates duplicate reporting by Cancer Centers
- Assures consistency
  - CTRP includes the NCT ID and a consistent title for each clinical trial
  - More uniform application of trial characteristics (e.g., primary purpose, phase)
- Improves accuracy
  - Only one registration record exists in CTRP for each trial or study
  - Each accrual is uniquely represented, supporting more accurate accrual reporting across trials
- Supports portfolio analysis across Cancer Centers

CTRP-Generated Data Table 4 for Interventional Trials
Progress to Date

- CTRP-generated DT4 for interventional trials first produced in 2014
- Reviewed and reconciled in 3 rounds of calls with Cancer Centers from 2014-2017
- Centers are now able to run CTRP-generated DT4 reports independently
- Comparison of CTRP-generated and Center-generated DT4 in 2017 for a comparable time period showed increasing agreement
- The CTRP-generated DT4 report for the period 1/1/16 –12/31/16 sent to each Cancer Center Director in May, 2017
- Utilization of CTRP-generated DT4 reports for non-competing CCSG grant applications began in October 2017[1]
- To date, more than 75% of the NCI Designated Cancer Centers have submitted non-competing renewal grants with a CTRP-generated DT4

[1] https://deainfo.nci.nih.gov/advisory/ctac/1117/minutes.pdf; https://deainfo.nci.nih.gov/advisory/ctac/1117/1-CTWGreport.pdf

CTRP -Generated DT4 Categories of Feedback

- Harmonization
  - Definitions, e.g., Trial Phase, Status
- Workflow
  - Reporting on Multi-institutional Trials

CTRP-Generated Data Table 4 for Interventional Trials
Harmonization: Trial Phase

- CTRP Trial Phases match those in ClinicalTrials.gov.
- Valid Trial Phases include:
  - Early Phase I (previously Phase 0)
  - I
  - II
  - III
  - IV
  - N/A

  } And combinations of these phases

- CTRP supports Pilot Y or N for trials of all Phases
- CTRP does not support Feasibility as a Phase as it is no longer a valid phase on the CCSG DT4 specification

Definitions: https://wiki.nci.nih.gov/display/CTRPdoc/Trial+Phase+Value+Definitions

CTRP-Generated Data Table 4 for Interventional Trials Harmonization: Trial Status

- **"Open" statuses in CTRP include:** Active, Available, Enrolling by Invitation, Temporarily Closed to Accrual, Temporarily Closed to Accrual and Intervention, Temporarily Not Available
  - If the status of a trial at a site is Temporarily Closed for the entire reporting period, it will be **included**
- If a Center is not "open" during the reporting period, the trial does not appear on CTRP-generated DT4, even if the Center is the Lead Organization
- The CTRP DT4 includes the **Overall Trial Status Open and Closed dates**, which may differ from a Center's Open/Closed dates
  - CTRP-generated DT4 includes "Date Closed" even if the date is after the reporting period.
  - *CTRP-generated DT4 will be modified to include the date that the trial opened at the cancer center and the date that the trial closed in the cancer center.*

CTRP-Generated Data Table 4 for Interventional Trials Workflow

- A trial must be registered in CTRP to appear on CTRP-generated DT4
- A unique trial is registered only once in CTRP
  - CTRP DT4 does not support reporting of two or more trials with the same NCT ID; it can be reported only once
- A Cancer Center's Organizational components are the same for all trials and are defined by ***the Cancer Center, not by NCI or CTEP.***
- Each accrued patient is counted only once

CTRP-Generated Data Table 4 for Interventional Trials
Workflow: Data Source for Multi-Institutional Trials

- **Lead Organization** registers trial, including primary purpose**,** reports trial status and accrual data for all participating sites. *Exceptions*:
  - NCTN and NCORP trials: CTEP and DCP PIOs report status and participating site information
  - Industrial trials:
    - Trial level information is imported from ClinicalTrials.gov
    - Participating sites report the status of the trial in their site and accrual data for their site only. ***Pharmaceutical companies do not report to CTRP***.
- **Participating Centers** report:
  - Target Enrollment for their Center
  - Program Code
  - Local Trial ID (optional)

CTRP-Generated DT4 Feedback: Change in Work Flow
Workflow: Discrepancies in Multi-institutional Trials

- Participating sites disagree with the data reported by the Lead Organization
  - Incomplete accrual
  - Study type
  - Study source
  - Status dates
- Resolving data discrepancy requires contact with:
  - Lead Organization (Institutional trials)
  - CTEP (National trials)
- CTRP Generated DT4 enables submitter to annotate each trial record

CTRP-Generated Data Table 4 for Interventional Trials
References

- **Data Elements** (definitions aligned to each DT4 column header)
  - CTRP DT4: https://wiki.nci.nih.gov/display/CTRPdoc/Data+Elements+Included+in+the+CTRP+Data+Table+4+Report
  - CCSG DT4: https://cancercenters.cancer.gov/GrantsFunding/eData#dt4

CTRP-Generated Data Table 4 for Interventional Trials

Recent CTRP Updates - Managing Data Table 4 Information for Your Center

- Cancer Center's now have the ability to update center-specific data which appears on their CTRP Data Table 4 report in the CTRP Registration module
  - **Targeted Accrual** ("Your Center Total" on the CTRP DT4 report)
    - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Targeted+Accrual
  - **Program Codes**
    - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Program+Codes
  - **Local Trial IDs** (optional)
    - https://wiki.nci.nih.gov/display/CTRPdoc/Managing+Local+Trial+IDs
  - **Specifying a Principal Investigator** (optional)
    - Ability for a Cancer Center to designate a trial-specific Principal Investigator *associated with their center* to appear on their CTRP DT4 (e.g., doesn't change the PI listing on the overall trial record)
    - https://wiki.nci.nih.gov/display/CTRPdoc/Specifying+the+Center+Principal+Investigator

CTRP-Generated Data Table 4 for Interventional Trials
Recent CTRP Updates (Cont'd)

- **Abbreviated and Other Trials: Summary Accrual Editing and Viewing**
  - Accrual Participating Site Subject Accrual Count page now provides Cancer Centers with the ability to Add, View, and Edit summary accrual information; # of Subjects Enrolled and Cut-Off Date
    https://wiki.nci.nih.gov/display/CTRPdoc/Recording+and+Updating+Participating+Site+Accrual+Counts

- **Missing Accrual**
  - CTRP counts all accrual reported regardless of status, except for "Withdrawn" trials/sites

CTRP-Generated Data Table 4 for Interventional Trials
CTRP Planned Updates (FY 19)

- Request CTEP to add “Locally Closed” site status for National trials
- CTRP DT4 report to be enhanced to include Local/Site Open/Closed dates
  - CTRP is reviewing design as a Center can have multiple Participating Sites on a trial
- New Total Accrual “Entire Study Accrual To Date” Column

Table 4 Report (Interventional)					Cancer Center:								
Clinical Research Category	Study Source	Specific Funding Source	Primary Site	NCT ID	NCI ID	Entire Study	Your Center Total	Center Reporting Period	Center to Date	Other Reporting Period	Other to Date	Entire Study Accrual To Date	Comments
INT	I	Center	Multiple	NCT#####	NCI ####-	60	50	0	46	0	0	56	
INT	N	Childrens	multiple	NCT#####	NCI ####-		90	13	76	0	0		

If Lead Organization: 56 is shown as “Entire Study Accrual to Date” as there is 46 accrual from Example Cancer Center and 10 from a different center that was not directly connected to Example Cancer Center

If Participating Site: Blank as this is a National study. This field would only be populated if the Example Cancer Center is the Lead Organization (same rule as “Entire Study” indicating Overall Trial target accrual)

CTRP-Generated Data Table 4 for Interventional Trials:
Next Steps

- Implementation for competing applications is delayed until FY20 (Oct 1, 2019)
- Continue submission for non-competing applications
  - Enables all centers (including those who submitted competing applications in FY18) the opportunity to submit a non-competing CTRP-generated DT4 in FY19
  - Provides additional time to:
    - Reconcile differences between CTRP-generated DT4 and center reported data
    - Harmonize business rules and definitions
    - Encourage development of services by CTMS vendors to facilitate CTRP reporting
- Timeline for implementation of CTRP-Generated DT4 for non-interventional studies to be determined

CTRP-Generated Data Table 4 for Interventional Trials:
Next Steps (Cont'd)

- Explore opportunities to share CTRP Coordinator contact information *between Cancer Centers* in a more collaborative and controlled manner
  - Participating Sites on Multi-Site Trials (Institutional and Externally Peer Reviewed trials)
    - Contact CTRO (NCICTRO@mail.nih.gov) for CTRP Coordinator contact information

- Next CTRP DT4 User Group Call to be scheduled for September 2018
  - Details to be communicated via the CTRP Listserv

CTRP Support/Listserv Additions

- Please contact the CTRP Engineering team for support related questions and/or inquiries:
  - CTRP_Support@mail.nih.gov

- To join the CTRP Users Listserv:
  - https://list.nih.gov/cgi-bin/wa.exe?SUBED1=ctrp-users-l&A=1

Suggested Topics for Next Meeting (September 2018)

- Thanks for attending!!

- Please send any suggested topics for future meetings to us at the following:
  - NCICTRO@mail.nih.gov

www.cancer.gov

www.cancer.gov/espanol

CTRP-Generated Data Table 4 for Interventional Trials
Recent CTRP Updates

- **Multi-Institutional Trials:** Changed implementation of multi institutional trial from one that enrolls participants from two different cancer centers to one that enrolls participants from two or more institutions which are not part of the same cancer center